

# Listening Session Leaders

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**Richard Wolitski, Ph.D.**

Acting Director, Office of HIV/AIDS &  
Infectious Disease Policy, HHS



**Amy Lansky, Ph.D., M.P.H.**

Acting Director  
Office of National AIDS Policy  
The White House



**Nadine Gracia, M.D. M.S.C.E.**

Deputy Assistant Secretary for Minority  
Health and Director, Office of Minority  
Health, HHS

# HHS Listening Session

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**Ken Almanza**

Program Associate-Treatment



# What are the current barriers to improving PrEP use?

- Lack of culturally competent medical services for people of color
- Low health literacy and limited knowledge about health insurance eligibility across many communities
- Although undocumented persons can obtain medication through assistance programs, they do not have a clear or sustainable access point to pay for lab tests/doc visits. They are shut out of the ACA marketplace and government funded programs
- No official access point for youth under the age of 18
- Concerns about confidentiality for young adults (under 26) who utilize parents insurance to access PrEP
- Lack of advocacy and lack of knowledge about PrEP among general primary care providers
- Some medical providers are still uncomfortable prescribing HIV medications to HIV negative patients
- Lack of safe spaces to discuss sexuality openly and honestly
- Stigmatizing inclusion/exclusion criteria for accessing PrEP
- Lack of dedicated, knowledgeable staff to help guide patients through assistance programs and choosing insurance plans that complement PrEP related medical services

# What are your recommendations for priority activities to expand use of PrEP

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- Culturally responsive programs that reach out to POC and support their adherence to PrEP
- Comprehensive PrEP navigator training programs, in-person and online
- Comprehensive health insurance training, in-person and online
- Comprehensive medical provider training on the use of biomedical prevention
- Capacity building on how to start and maintain PrEP programs
- On-going webinars/updates to share best practices among FQHC's, health centers and CBO's
- Establish a clear access point for youth under the age of 18
- Establish confidentiality protection for persons under 26 who utilize parents insurance
- Increase discussion about sexuality, gender identity and culture as it relates to medical care
- Establish a National Biomedical Prevention Task Force

# NEW METHODS OF BIOMEDICAL PREVENTION

Brian Risley, MFA  
Director, Programs and Education  
Men's Health Foundation  
Los Angeles, California



SoCal **MMG**  
MENS MEDICAL GROUP



MENS **HEALTH**  
FOUNDATION



MILLS **CLINICAL**  
RESEARCH

# NEW METHODS OF BIOMEDICAL PREVENTION – PrEP DELIVERY

- Currently, there is real need for new delivery systems of PrEP that can satisfy the estimated 1,200,000 MSM, IDUs, TGs and heterosexuals at substantial risk for acquiring HIV with PrEP indications\*.
- Taking a daily pill should not be our best and only option due to adherence concerns.
- PrEP of the future may look much like birth control does today, with an array of options for individuals to choose from, that include multiple oral medications, long-acting injectable PrEP, a long-term implant placed under the skin (known as a subdermal implant), and even long-acting PrEP that uses naturally occurring antibodies rather than antiretroviral medications.

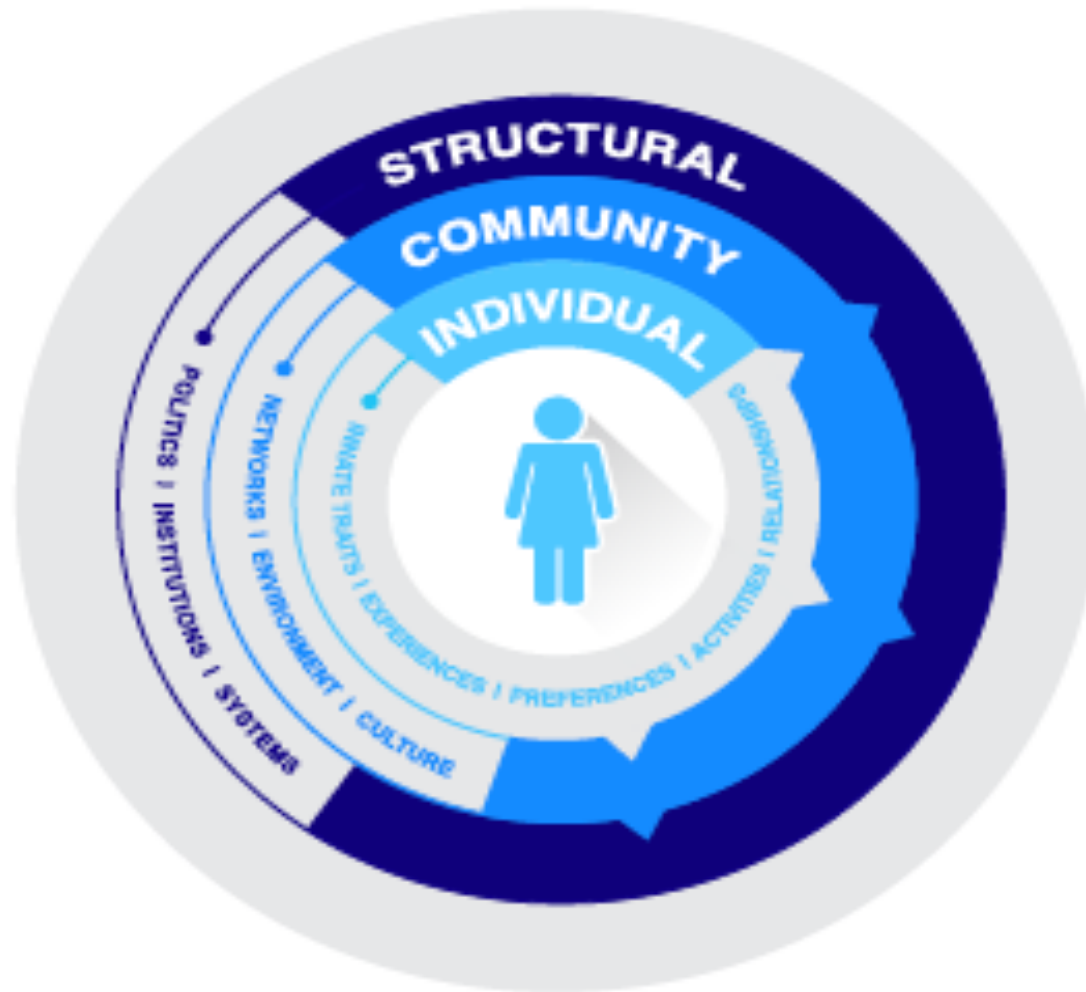
\* CDC MMWR

Vital Signs: Estimated Percentages and Numbers of Adults with Indications for Preexposure Prophylaxis to Prevent HIV Acquisition - United States, 2015

# NEW METHODS -- DEPOT PrEP & BNAs

- **HPTN 077** – Phase 2 safety study of injectable cabotegravir in HIV-uninfected low-risk men and women Q12W, N=160.
- **ÉCLAIR** – Phase 2 safety study of injectable cabotegravir in HIV-uninfected low-moderate risk men Q12W, N=120.
- **DEPOT PREP** -- Phase 3 study of injectable cabotegravir starting in mid 2016 for HIV-uninfected at-risk MSM Q8-12W.
- **BROADLY NEUTRALIZING ANTIBODIES** (BNAs, like VRC01) are highly effective at neutralizing a wide array of strains of the virus. BNAs can be manipulated to persist in the body so that their use as PrEP may only require injections every 4 or 6 months.
- **GOAL** -- Complete studies by 2019 and seek FDA-approval.

# Women vulnerable to HIV have similar needs to women living with HIV.





# Women vulnerable to HIV have access to limited services.

- HIV screening & prevention options
- Housing
- Intensive case management
- Substance use treatment
- Mental health services
- Directly observed therapy
- Childcare



# Chronic Disease Model -> Integrated Treatment & Prevention



# Erika Aaron, MSN

PrEP Clinical Advisor

AIDS Activity Coordinating Office, Phila Dept of Health

## Improve awareness of and access to PrEP

- Doing Better with programs such as 15-1509 and 15-1506
  - However this is only limited to certain jurisdictions and would benefit if expanded to new areas of high prevalence.
- The disproportionate impact of HIV on racial and ethnic minorities in the United States and the risk that these disparities could worsen if some people have greater difficulty than others obtaining PrEP.
- Full access to comprehensive PrEP services for those whom it is appropriate and desired should be standard of care and ensured.

# 1. What are the current barriers to improving PrEP use?

- Medication Access
- Lack of awareness of PrEP by providers and by the public

## 2. What are your recommendations for priority activities to expand use of PrEP?

### ■ Medication Access:

- *SPBP programs in every state*
- *ACA to include coverage of preventive services like HIV screening, now to include coverage of PrEP*
- *PrEP access to become a requirement for medical homes*
- *US Preventive Services Task Force to include PrEP coverage as an A and B Recommendation*

### ■ Lack of Awareness:

Federal Agencies such as the Office of HIV/AIDS and Infectious Disease Policy (OHAIDP), CDC, White House Office of National AIDS Policy, and the HHS Office of Minority Health all partner together in ensuring there are Federally supported

- *Public Service announcements for TV and radio,*
- *PrEP awareness campaign materials such as bill board announcements, public transportation placards,*
- *press statements for national distribution for newsprint and social media,*
- *PrEP awareness posters, brochures, etc nationally distributed to all primary care offices especially FQHC*

# *Local Health Departments & PrEP Implementation*

Presented by: Nicholas Parr, MPH  
*Senior Program Analyst – HIV, STI, & Viral Hepatitis*



# Barriers & Priority Activities

## Barriers to Improving PrEP Use

*Lack of:*

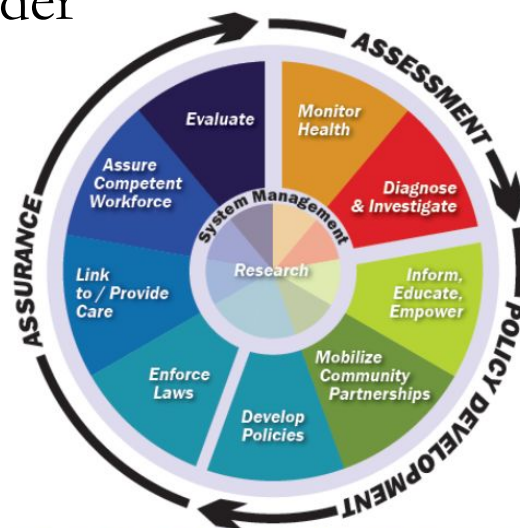
- Health care provider awareness and knowledge
- Resources at the local level to support capacity for PrEP programming and patient referral/navigation
- Methods for local assessments of the size of the population that might benefit from PrEP, and effective strategies for reaching these individuals

## Priority Activities to Expand Use of PrEP

- Health care provider education
- Develop and implement strategies to reach populations that are most likely to benefit from PrEP
- Increase resources, training, and capacity for PrEP referral and navigation
- Develop methods for assessing the size of the population that might benefit from PrEP, and for monitoring and evaluating coverage and impact
- Document and disseminate successful examples of PrEP implementation

# Local Health Department Roles

- Convene partners and coordinate efforts to implement PrEP
- Use local data to determine who might benefit from PrEP and inform program planning
- Educate and outreach to community members, health care providers, and HIV prevention partners
- Develop resource inventories, including provider directories
- Deliver PrEP through health department clinics
- Refer individuals to PrEP
- Conduct health insurance and financial navigation for PrEP
- Support PrEP adherence
- Provide funding and training to CBOs and other agencies to implement PrEP
- Monitor and evaluate PrEP use and impact





# PrEP: Opportunities

- With sufficient resources, provides opportunity for comprehensive and seamless sexual, public and medical health services for people who would benefit most from PrEP.
- Very early data suggests that early treatment of people living with HIV and retention in care, combined with PrEP in HIV-negative people can have a synergistic effect in controlling the epidemic.
- Could reduce stigma around HIV and sexuality.
- Provides an option that doesn't require a sex partner's cooperation.

# PrEP: Challenges

- Doesn't solve, and may exacerbate, historical health disparities. Getting PrEP to populations that could most benefit will require focus and targeted approaches
- New infections are climbing most in young people, yet FDA approval for use in people under 18 and drug access is almost completely unavailable to minors or to people who do not want PrEP services to appear on their parent's insurance statements.
- Drug access is a huge challenge despite a patched together "safety net" of insurance, public funding and pharmaceutical and non-profit co-pay and medication assistance projects.
- PrEP users may require a set of other social services, including housing, mental health and substance use, not currently available.
- Models for PrEP service-provision are all over the place. Who does intakes? Who writes scripts? How is continuing adherence and prevention support taking place and who provides them?
- PrEP is predominantly available in well-resourced GLBT health centers and STD clinics, or gay-friendly private doctors. Culturally and practically appropriate PrEP services for MSM of color, trans-women and trans-men and cisgender women are far harder to find – especially outside urban areas on the East and West Coast. How to adapt and disseminate?
- PrEP is expensive to deliver and partnerships between community and health care resources are often fragmented.
- Danger that health justice concerns could be minimized. How to avoid "medicalization" of prevention.

# How can the Federal Government Help?

- Form a central body to coordinate implementation science on PrEP dissemination strategies.
- Develop a mechanism, similar to Ryan White/ADAP, to assist community-based providers in assuring PrEP access to low-income individuals, including access to ancillary social services.
- Work with experts to set targets for PrEP awareness among groups at greatest risk for HIV and their providers, for the percentage of people seeking health services or HIV and STD testing who are offered PrEP, and for the number of clinics and providers who make PrEP available in a culturally competent manner.
- Change how the federal government and funded providers collect information about gender identity. (e.g. two-step method) – to affect how resources are targeted and funded.

# Gay City and End AIDS Washington

## **Tobi Hill-Meyer**



- A Multi-Racial Trans Woman With Nearly Two Decades Experience HIV/AIDS Organizing
- Communications Coordinator for Gay City
- Coordinator for End AIDS Washington Campaign
- Board Chair of Gender Justice League
- Directed Two Recent PrEP / Trans Videos

# King County Pride Survey Data

	All Cis MSM (n=631)	Trans Women (n=98)	Trans Men (n=66)
Heard of PrEP	69%	44%	58%
Taken PrEP	10%	7%	3%
Ever HIV tested	89%	77%	72%
Tested at least twice in the past two years	62%	33%	23%
Unstably Housed	6%	19%	21%
Transactional Sex	2%	14%	10%
Condomless sex with HIV pos/ status-unknown partner	0%	6%	9%



# Follow Up



## **Tobi Hill-Meyer**

- <http://vimeo.com/prepvideos>
- <http://EndAIDSWashington.com>
- <http://gaycity.org>

## **Contact Information**

**tobi@gaycity.org**  
**206-860-9232**



Established in  
March 2012

CDC: up to 500,000 women may need PrEP

But number of women getting PrEP has flat-lined!

2013: **42%** of all PrEP starters were women

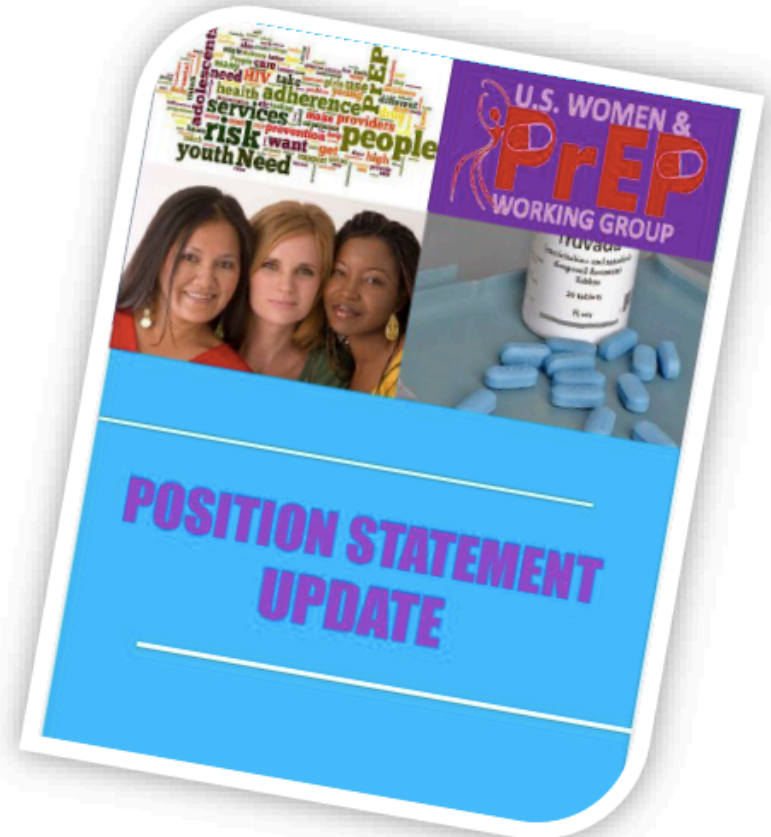
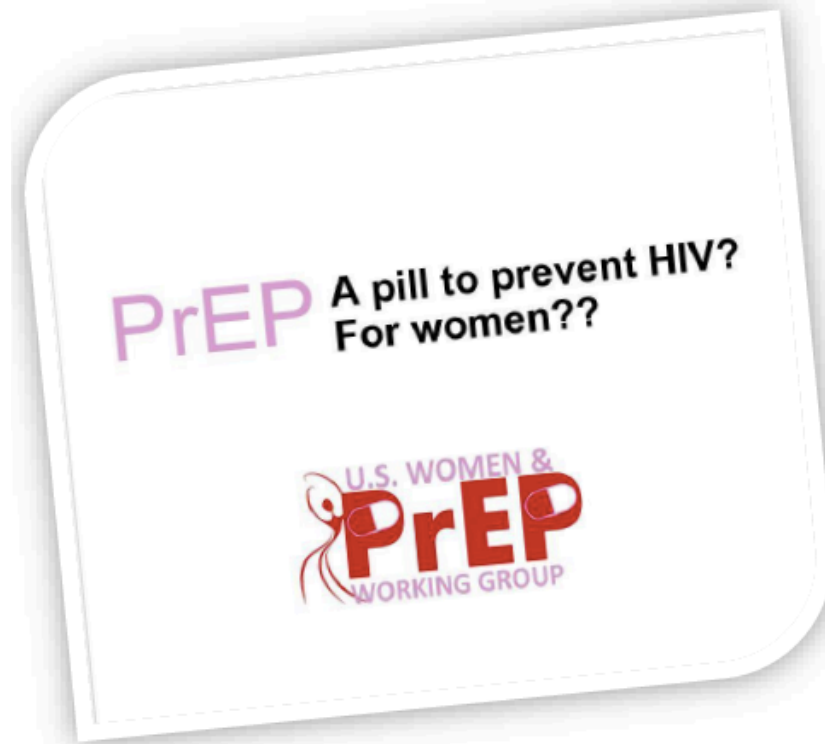
2015: **14%** (only about 700) of all new PrEP  
starters were women

# Key Aims of the Working Group

- ▶ Engage Civil Society in research and implementation of PrEP and microbicides
- ▶ Get a national/federal plan for community and provider education and social marketing of PrEP
- ▶ Incorporate PrEP education and access for women into the National HIV/AIDS strategy
- ▶ Include milestones, feedback mechanisms, resources and accountability in the above.



# Community Engagement Tools



<http://www.sisterlove.org/us-women-prep-working-group/>

# PrEP: Provider education & clinic capacity building



Sophy S. Wong, MD

Medical Director, Bay Area | North Coast AETC

# How do primary care providers (PCPs) feel about PrEP?

## National surveys show that:

### 1. PCPs lack of knowledge about PrEP

- Awareness is low but has increased from 24% in 2009 to 66% in 2015 (PLOS ONE, CDC/Smith et. al., June 2016)
- <40% of family planning providers correctly answered basic knowledge questions about PrEP in one survey of 342 potential prescribers (Contraception 2016; Seidman et. al.)
- HIV screening rates and testing knowledge is low

### 2. PCPs want to learn more and prescribe PrEP to people at high-risk for HIV

- 87% of family planning providers want more PrEP education
- 91% in DocStyles survey are willing to prescribe PrEP to at least one group at high-risk

## East Bay survey of PCPs on barriers to implementation:

- 99% have heard of and would offer PrEP, 80% would prescribe themselves
- Training needs: online resources, on-site trainings, phone/email consults
- **Implementation needs: systems & support staff trained on med coverage and coordination of refills and follow-up labs/visits**

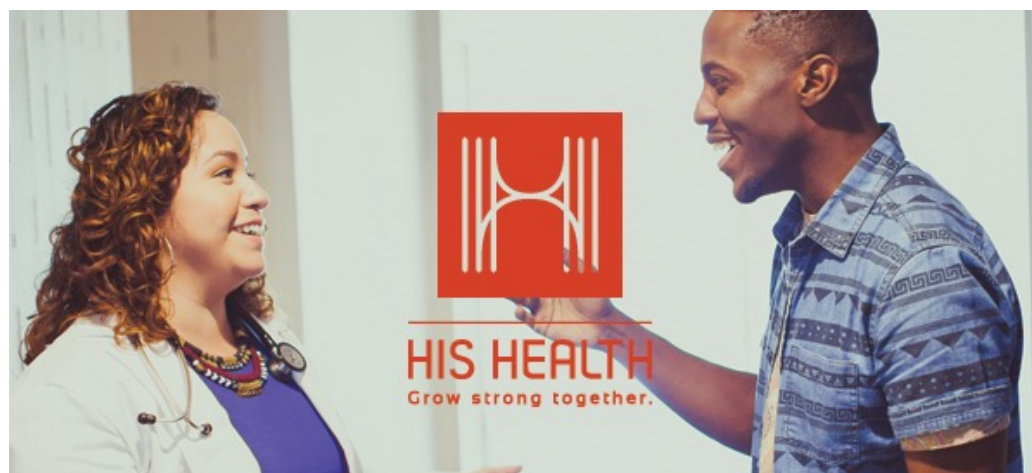
# How can we increase PrEP access through provider training and clinic capacity building?

1. **Coordination of PrEP CBA providers to develop standards** and outcome metrics/evaluation with a holistic approach for:
  - **Buy-in with administrators and leadership** on work flows, staffing, trainings
  - **Team-based training:** clinicians alongside support staff
2. **Accessible, updated online tools/references in one place:** on insurance coverage, clinical updates, PrEP referrals
3. **Work flow & clinical protocols** that can be easily adapted for local clinics
4. **On-going support for learning networks** of PrEP navigators and support staff: sharing strategies & best practices

# NASTAD'S FOCUS ON PrEP

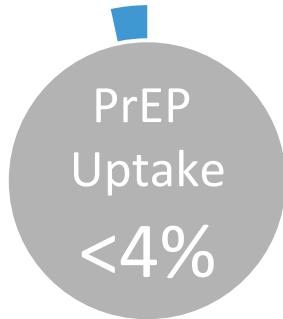


- Private and public insurance enrollment
- Coordination between HIV prevention and care
- Engagement with healthcare systems
- Provider education with a focus on serving young African American men who have sex with men



# BARRIERS

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## Funding Gaps

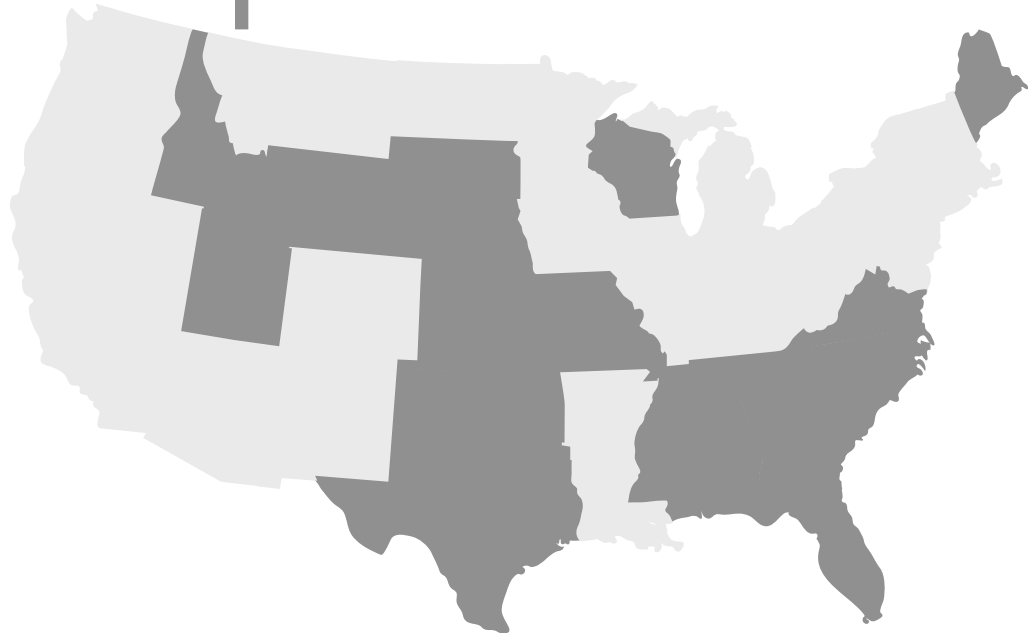
No safety net for  
vulnerable individuals

## High Cost

Co-payments for a specialty-tier  
medication and high deductibles  
Existing social determinants

## Medicaid Expansion

19 states have not expanded Medicaid



# RECOMMENDATIONS

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Federal partners should support a range of delivery and financing mechanisms aimed at securing a focused safety net.

## ■ STD Clinics

Reaching individuals not engaged in primary care  
Maximizing community-based partners

## ■ Community Health Centers

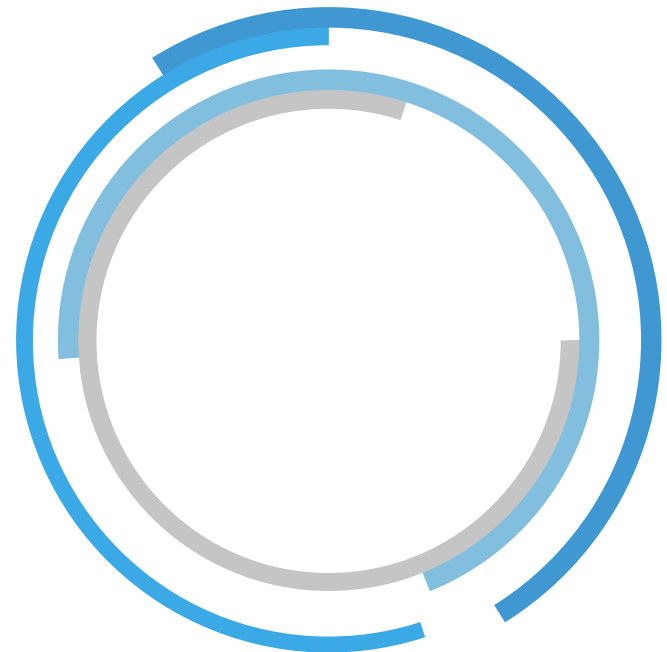
Focused comprehensive PrEP programs

## ■ PrEP Assistance Programs

Interwoven community support  
Assistance in accessing health insurance

## ■ Evaluation

Improvement and support for emerging models



# Listening Session on Pre-Exposure Prophylaxis (PrEP)

*HHS Office of HIV/AIDS & Infectious Disease Policy, HHS  
Office of Minority Health, and White House Office of  
National AIDS Policy  
June 20, 2016*

*Nick Taylor  
Policy Associate*



THE AIDS INSTITUTE



# Importance of PrEP Education and Awareness

- The CDC should continue to lead on PrEP awareness and education
  - Incorporated into grantees' high impact prevention activities, general HIV education & outreach, testing programs, and surveillance programs
- We support \$20 million set aside in President's FY17 budget for PrEP and related services
  - Would like to see how funds will be spent and mechanism used to purchase PrEP
- STD clinics effective way to identify new PrEP consumers and link them to PrEP. If an individual requests a HIV test in a HIV or STD clinic, a syringe service program, or other settings where testing occurs, they should automatically be provided information on PrEP
- Continue to promote medication/copay assistance programs
- Government and public health leaders and officials, U.S. Public Health Commissioned Corps, & provider associations should all be educated and ready to provide public with information on PrEP
- Education for young people should be prioritized; FDA approval for < 18

# Addressing Coverage Barriers to PrEP

- Take Advantage of existing payers that cover PrEP & PrEP Services
  - Private Insurance, Medicaid and Medicare
- Overcome existing barriers
  - CCIIO should recommend that states review Qualified Health Plan formularies for coverage of PrEP, high cost-sharing and excessive prior authorization requirements
  - CMS should promote PrEP access through Medicaid by pushing states to expand Medicaid, informing state Medicaid directors that PrEP is an effective prevention method, and encouraging states to put PrEP on their preferred drug lists.
- USPSTF review PrEP as an “A” or “B” grade preventive service
- Ryan White Program should examine opportunities to increase access and education
  - Review current law to determine what it can currently do to assist in providing PrEP
  - Examine statutory changes that can be made to address needs of HIV-negative individuals, but not supplant providing care and treatment to those who are living with HIV
- HHS issue guidance for community health centers, family planning, and STD clinics on how they can utilize and coordinate multiple sources of funding, including 340B, to cover PrEP and PrEP services.

# PrEP at WWH

## **Integrating PrEP into Primary Care at a Federally Qualified Health Center in Washington DC**

Mission is to be the highest quality, culturally competent community health center serving greater Washington's diverse urban community, including individuals who face barriers to accessing care, and with a special expertise in LGBT and HIV care.

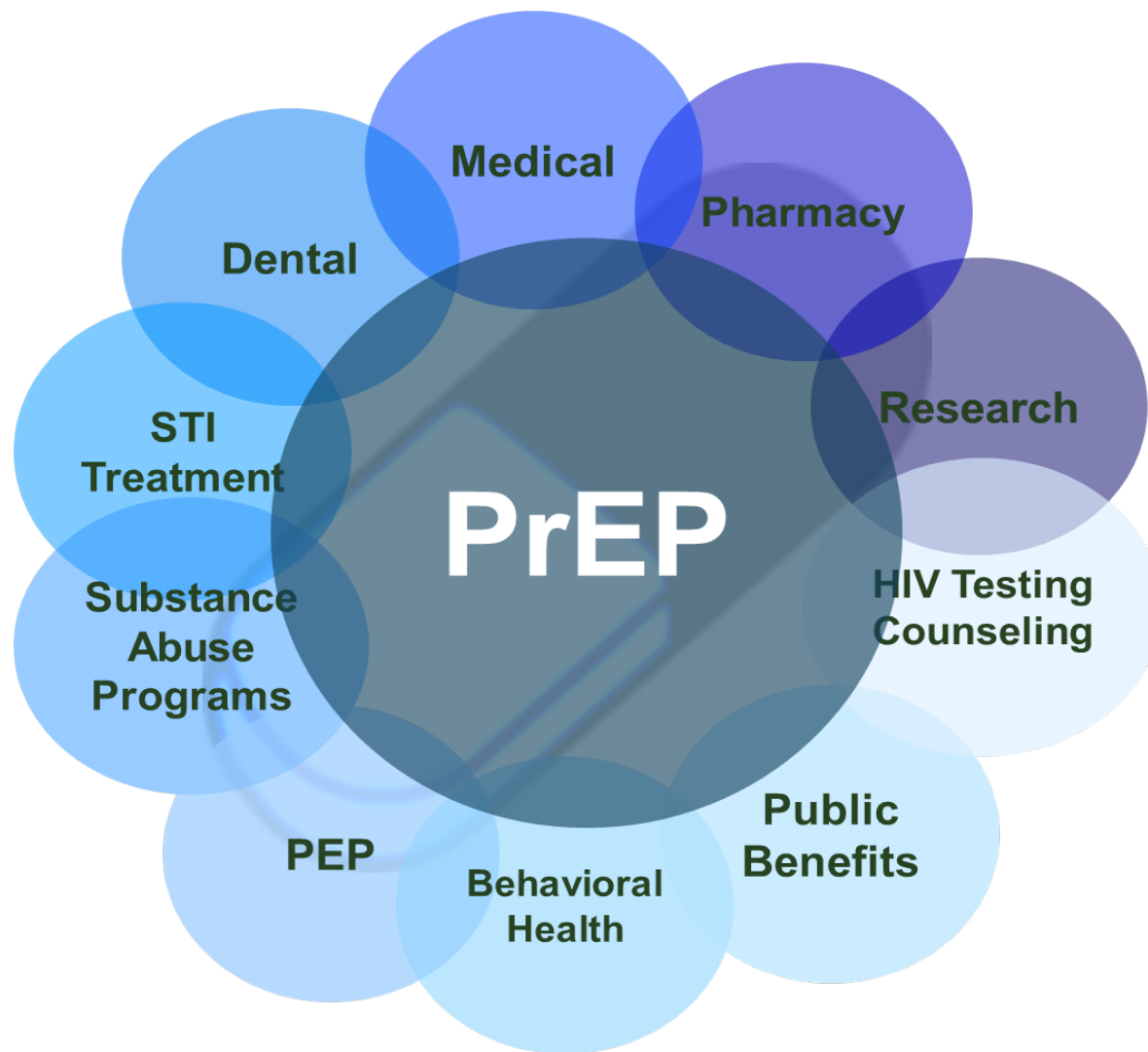
**Megan Coleman, FNP**

*Director of Community Research*

**Whitman Walker Health**



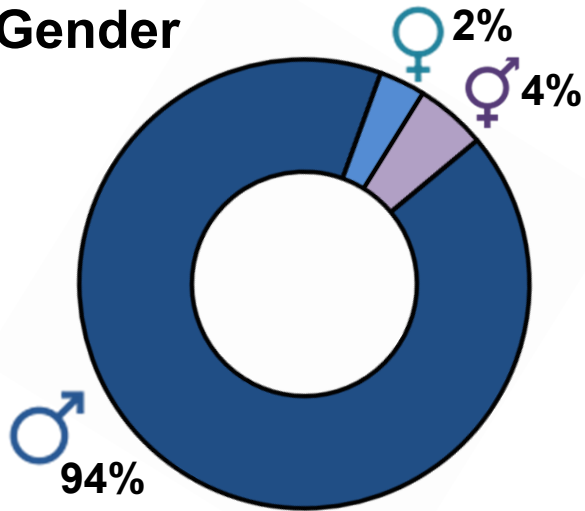
**PrEP Program has become integrated into all aspects of care at WWH; serves as engagement into Healthcare system**



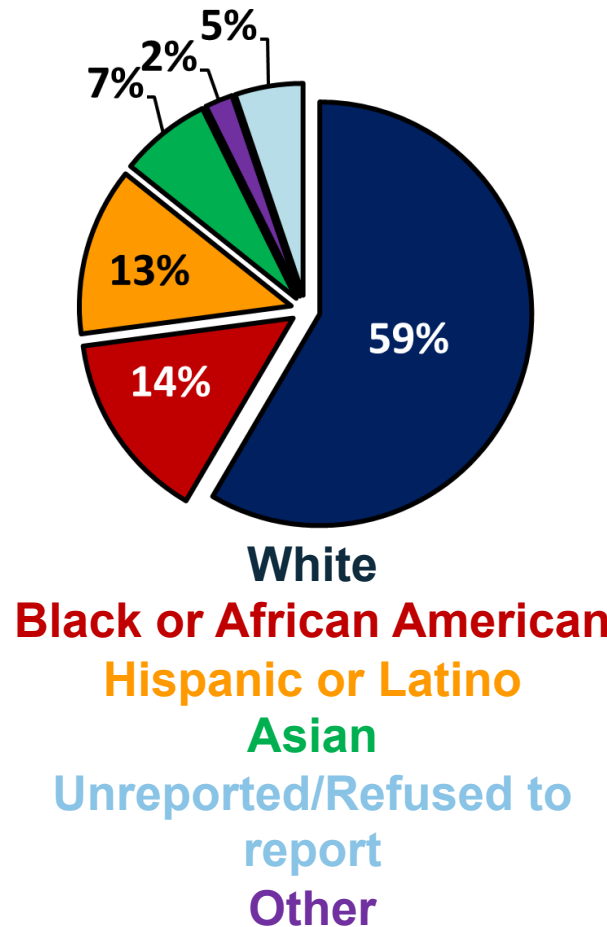
# Current PrEP Population at WWH= 616

Averaged 35 new PrEP/Primary Care Patients a month in 2015

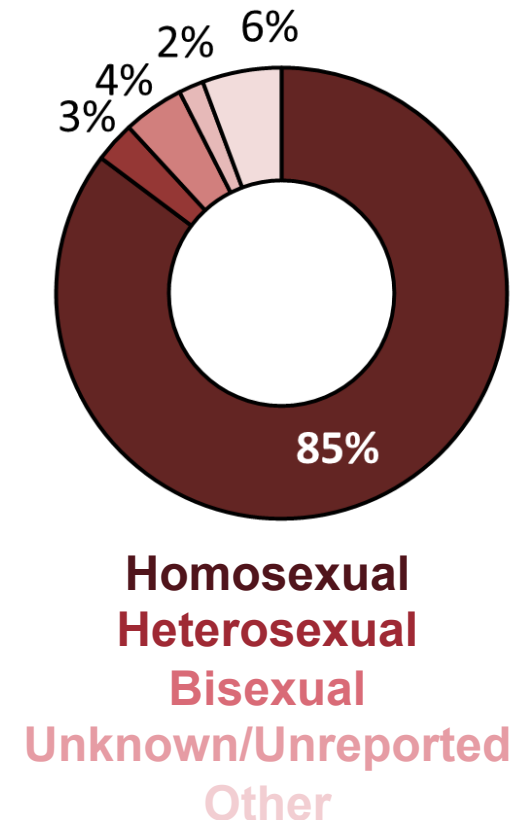
**Gender**



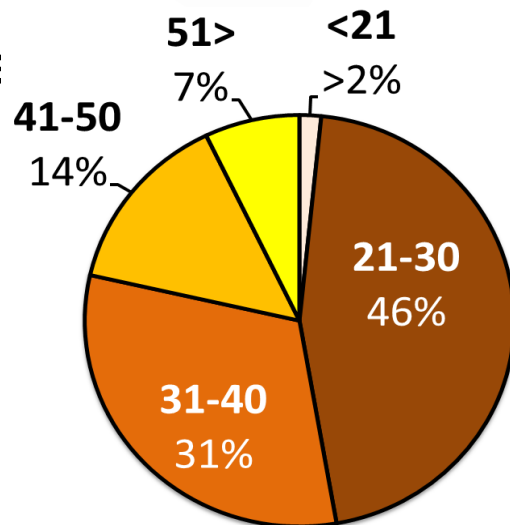
**Race**



**Sexual Orientation**



**Age**



(Last Updated: June 2016) \*





A close-up photograph of a man's face, slightly out of focus, as he holds a small, blue, oval-shaped pill between his thumb and index finger. The pill has the letters 'T01' embossed on it. The background is a soft, warm-toned interior. A dark blue horizontal band is overlaid across the middle of the image, containing the text 'Looking Ahead' in white.

# Looking Ahead

# Listening Session Written Comments

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The following are additional submissions from individuals who were not able to speak during the PrEP listening session.

## PrEP Comments

I am an Infectious Disease physician in New Haven, Connecticut. I practice at Fair Haven Community Health Center, a federally qualified health center that services a largely Hispanic community. I practice HIV care and am a PrEP champion. As with the HIV continuum of care, the PrEP cascade faces challenges in identifying high risk individuals, linkage to care and medication adherence. Before we understand and address those issues, however, we need to actively increase awareness of PrEP among the public and medical providers. Truvada has been approved for HIV pre-exposure prophylaxis since 2012. Four years later clinicians are unfamiliar with PrEP and unable to educate patients or prescribe PrEP. The public remains generally uninformed, including members of high risk communities including young minority MSM.

While we may face challenges with PrEP uptake and adherence, we have a clear opportunity and obligation to inform the public and the medical community. Frankly, this is not hard to do. The reason that federal, state and local public health campaigns have been limited is likely related to the perceived sensitivity of discussing HIV risk behaviors and HIV prevention. If we had an HIV vaccine, we would have front page articles, commercials, billboards, mailings and every form of public communication.

If we think back to the early 1980s, the federal government was reluctant to talk about HIV/AIDS for similar reasons. As a result, opportunities to inform the public and protect individual and public health were lost. We should not repeat history but should implement an all out effort to ensure that everyone is aware of PrEP. There will be eventual challenges but, until we have an informed public and medical community, we are missing critical opportunities to prevent future HIV infections.

Thank you for the opportunity to share this opinion.

Sincerely,

Krystn Wagner, MD PhD

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My name Denis Smith,

I am a long time survivor of AIDS. I am the CEO of the Consumer Advisory Council Network. I am in favor of PrEP and condom use. The current barriers in South Carolina is the lack of education, how PrEP is introduced and advertised to the public and the HIV community under prevention. I spoke to a DHEC official about integrating a message as a preventative and intervention. The response I got, I was not expecting; they did not expand Medicaid. This is a big concern too me.

I have an outline program that I am working on to integrate PrEP and Condom use. To educate and empower my peers and the public on the benefits of using PrEP.



1. Reducing the number of new cases.
2. Prevention and intervention: of ending AIDS by 2020.
3. Helping to left stigma and the decriminalizion associated with living with HIV/AIDS.

I want to thank you for taking time out to read my comment. Have a great day.

Ms. Smith